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Guidance for Industry
And
FDA Employees
Regulatory Procedures Manual
Chapter 9

Subchapter:
COMMUNICATION CONCERNING
ASSESSMENT OF CIVIL MONETARY
PENALTIES BY U.S. CUSTOMS SERVICE IN
CASES INVOLVING IMPORTED FOOD

This guidance does not create or confer any rights, privileges, or benefits for, or on, any person and does not operate to bind FDA, U.S. Customs or the public. This guidance is being distributed in accordance with the FDA's policy for Level 2 guidance documents as set out in the agency's Good Guidance Practices, published in the Federal Register of February 27, 1997 (62 FR 8961).

Comments and suggestions regarding this document should be submitted by [date] to Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr. rm. 1-23, Rockville, MD 20857. After [date] submit comments to Joseph L. McCallion, Division of Import Operations and Policy (HFC-170) 5600 Fishers Lane, Rockville, MD 20857. For questions regarding this document contact Joseph L. McCallion, (301) 443-6553.

U.S. Department of Health and Human Services
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REGULATORY PROCEDURES MANUAL - CHAPTER 9

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NOTE: For the purpose of this subchapter, all references to foods include both human and animal foods.

PURPOSE: To ensure that FDA is aware of the assessment, by Customs, of civil monetary penalties against violators in cases involving unsafe food and that Customs is aware of any events for which civil monetary penalties are an appropriate regulatory action.

BACKGROUND: Customs has enforcement programs under existing statutory authorities that allow for the imposition of civil penalties. Under 19 U.S.C. 1592, Customs may impose a civil penalty against any person who by fraud, gross negligence, or negligence, enters, introduces, or attempts to enter or introduce, any merchandise into the United States by means of any document or electronically transmitted data or information, written or oral statement, or act which is material and false or by means of any omission that is material. Civil penalties can be assessed in amounts up to the domestic value of merchandise so imported. Under 19 U.S.C. 1595a(b), Customs may assess a penalty against any person who directs, assists financially or otherwise, or is in any way concerned with introducing, or attempting to introduce any article into the United States contrary to law. Penalties assessed under 1595a(b) also may be in an amount equal to the domestic value of the merchandise. Customs has assessed penalties against importers that substitute, rather than export merchandise that FDA has refused. While this procedure is currently in operation at Customs, FDA district offices do not always

provide adequate information to Customs for assessment of a civil penalty. Conversely, FDA is not always kept aware of Customs' assessment of civil monetary penalties involving importation or exportation of food.

GUIDANCE: FDA districts should alert the local Customs Port Director when a situation is encountered for which assessment of civil monetary penalties may be appropriate under the above authorities. FDA districts should coordinate with their local Customs office to make sure Customs informs the local FDA office of the imposition of civil monetary penalties involving the entry or attempt to enter any FDA-regulated food product. Customs should, in turn, develop procedures to receive recommendations for, and to inform FDA of, the imposition of civil penalties for violative importations of food.

FDA districts should meet with local Customs quarterly to discuss enforcement actions, including civil monetary penalties. FDA districts should provide a quarterly report to DIOP identifying jointly conducted enforcement actions and/or assessments of civil monetary penalties against importers of FDA-regulated foods.